

PATIENT INFORMATION
IMAAVY™ [im-AH-vee]
(nipocalimab-aahu)
injection, for intravenous use

What is IMAAVY?

IMAAVY is a prescription medicine used to treat adults and children 12 years of age and older with a disease called generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

It is not known if IMAAVY is safe and effective in children under 12 years of age.

Do not receive IMAAVY if you:

- have a history of a severe allergic reactions to nipocalimab or any of the ingredients in IMAAVY. Reactions have included angioedema and anaphylaxis. See the end of this Patient Information leaflet for a complete list of ingredients in IMAAVY.

Before receiving IMAAVY, tell your healthcare provider about all of your medical conditions, including if you:

- ever had an allergic reaction to IMAAVY. Ask your healthcare provider if you are not sure.
- have or have had any recent infections or have any symptoms of infection.
- have recently received or are scheduled to receive an immunization (vaccine). People who are being treated with IMAAVY should not receive live vaccines.
- are pregnant or plan to become pregnant. It is not known whether IMAAVY will harm your unborn baby.
 - **Pregnancy Safety Study.** There is a pregnancy safety study for IMAAVY if IMAAVY is given during pregnancy or you become pregnant while receiving IMAAVY. Your healthcare provider should report IMAAVY exposure by contacting Janssen at 1-800-526-7736 or www.IMAAVY.com.
- IMAAVY can pass into your breastmilk and it is not known whether IMAAVY will harm your baby. Talk to your healthcare provider about the best way to feed your baby if you receive IMAAVY.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive IMAAVY?

- IMAAVY will be given to you by your healthcare provider through a needle placed into your vein (intravenous [IV] infusion).
- You will receive a starting dose of IMAAVY infusion lasting at least 30 minutes. Two weeks later you will receive your next dose of IMAAVY infusion lasting at least 15 minutes. Your following doses will be given every two weeks.
- If you have a reaction during your IMAAVY infusion, your healthcare provider may decide to give IMAAVY more slowly or to stop your infusion.
- If you miss a scheduled IMAAVY infusion, you should receive your next dose as soon as possible.

What should I avoid while receiving IMAAVY?

- You should not be given live vaccines while receiving IMAAVY.

What are the possible side effects of IMAAVY?

IMAAVY may cause serious side effects, including:

- **Infections.** Infections are a common side effect of IMAAVY that can be serious. Receiving IMAAVY may increase your risk of infection. Tell your healthcare provider right away if you have any of the following symptoms of infection:
 - fever
 - chills
 - shivering
 - cough
 - sore throat
 - fever blisters
 - burning when you urinate
- **Allergic (hypersensitivity) reactions.** Allergic reactions may happen during or up to a few weeks after your IMAAVY infusion. Get emergency medical help right away if you get any of these symptoms during or after your IMAAVY infusion, which may be part of a serious allergic reaction:
 - swelling of your face, lips, mouth, tongue, or throat
 - difficulty swallowing or breathing
 - itchy rash (hives)
 - chest pain or tightness
- **Infusion-related reactions.** Tell your healthcare provider right away if you get any of the following symptoms during or a few days after your infusion of IMAAVY:
 - headache
 - rash
 - nausea
 - fatigue
 - dizziness
 - chills
 - flu-like symptoms
 - redness of skin

The most common side effects in people with gMG treated with IMAAVY include:

- infection in parts of your body that you use for breathing (respiratory tract infection)
- swelling in your hands, ankles, or feet (peripheral edema)
- muscle spasms

These are not all of the possible side effects of IMAAVY.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of IMAAVY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

You can ask your pharmacist or healthcare provider for information about IMAAVY that is written for health professionals.

What are the ingredients of IMAAVY?

Active ingredient: nipocalimab-aahu

Inactive ingredients: arginine hydrochloride, histidine, L-histidine monohydrochloride monohydrate, methionine, polysorbate 80, sucrose, and water for injection.

Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, USA

U.S. License Number 1864

For patent information: www.janssenpatents.com

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For more information, call 1-800-526-7736 or go to www.IMAAVY.com